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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/718,976	11/20/2003	Syed F.A. Hossainy	50623.317	2726

7590 02/03/2009

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EXAMINER	
ROGERS, JAMES WILLIAM	

ART UNIT	PAPER NUMBER
1618	

MAIL DATE	DELIVERY MODE
02/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/718,976	HOSSAINY ET AL.	
	Examiner	Art Unit	
	JAMES W. ROGERS	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-8,13,14,16-21,23-26,31,32 and 34-36* is/are pending in the application.

4a) Of the above claim(s) *13,14,31 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-8,16-21,23-26 and 34-36* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/25/2008 has been entered.

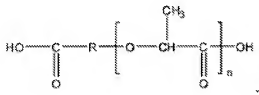
Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-3,5-8,16-21,23-26,34-36 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claims are drawn to a medical article comprising an implantable substrate having a coating the coating includes a polymer or copolymer containing a carboxylated poly(lactic acid) (PLA) that contains the following structure:



where R is a group from a hydroxyl acid

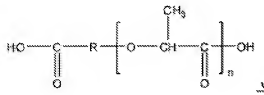
HO-R-COOH.

The instant specification fails to provide information that would allow the skilled artisan to practice the prevention of the instant invention. Attention is directed to *In re Wands*, 8USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

(1) the nature of the invention; (2) the breadth of the claims; (3) the state of the prior art; (4) the predictability or unpredictability of the art; (5) the relative skill of those in the art; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

(1) The nature of the invention;

The claims are drawn to a medical article comprising an implantable substrate having a coating the coating includes a polymer or copolymer containing a carboxylated PLA that contains the following structure:



where R is a group from a hydroxyl acid

HO-R-COOH.

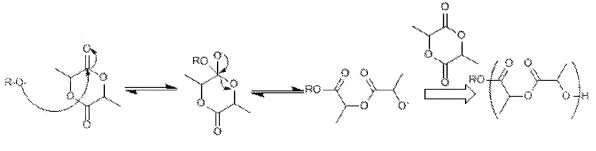
(2) The breadth of the claims:

Claims 1-3,5-8,16-21,23-26,34-36 embraces a medical article that comprises a substrate and a coating comprising a carboxylated PLA.

(3) The state of the prior art:

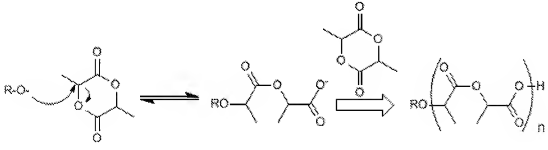
The state of the art regarding PLA polymers produced by ring opening polymerization of lactide with a ring opening catatlyst such as applicants claimed hydroxy acid is very high. However, the state of the art for a catalyst which reacts with the alpha methylated carbon instead of the carbonyl group on the lactide is very low or does not exist. For instance it is well known in the art that a nucleophilic catalyst such as an alkoxide anion will react with lactide via a ring opening process as shown in the scheme below:

Scheme 1



The examiners position is well known and supported within the art, some of the numerous teachings on lactide ring openings are found within the references cited. Ovitt et al. J. Am Chem. Soc., 1999, 121 (16), 4072-4073 and Odian, Principles of Polymerization, 3rd edition, John Wiley and Sons, INC, pages 569-572. However it is not well known that a nucleophile such as an alkoxide can react and open lactide by nucleophilic attack on the methylated alpha carbon as shown below:

Scheme 2



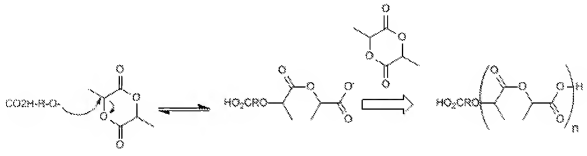
It is noted that in order for applicant's claimed carboxylated PLA to form the claimed structure the hydroxy acid would have to attack the methylated alpha carbon in a similar manner to scheme 2. In fact if R is substituted for –R-COOH scheme 2 would be the same as applicants claimed carboxylated PLA.

(4) The predictability or unpredictability of the art:

As described above ring opening polymerizations of lactide is a mature field and it is well known that such ring opening occur by nucleophilic attack of the carbonyl atom in the lactide ring. However it is not known and therefore it cannot be considered predictable that a nucleophilic species would react with the methylated carbon on the lactide ring instead of reacting with the electrophilic carbonyl carbon on the lactide ring

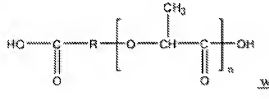
which is the expected result that the art teaches. Note that the only way applicant's polymer could be made is by the hydroxyacid nuclephilically attacking the alpha methylated carbon on the lactide ring as shown in the scheme below:

Scheme 3



(6)-(7) The amount of direction or guidance presented / working examples:

In the instant case, the guidance of the specification as to how the hydroxy acid is capable of producing the claimed carboxylated PLA which appears to be counterintuitive as to what the teaching of the art would suggest is completely lacking. The specification as filed does not speak on or show any working examples or any studies performed that confirm that the connectivity of the carboxylated PLA as claimed. As noted above in order to produce a carboxylated with the claimed structure shown below:

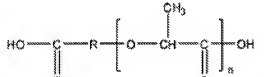


where R is a group from a hydroxyl acid HO-R-COOH.

the hydroxy acid would have to react in some way with the methylated alpha carbon on the lactide ring, a result which would not be expected nor could it be considered as predictable since the teachings of the prior art would suggest that any nucleophilic substitution on a lactide ring would occur at the carbonyl carbon. The specification does not teach how or why the hydroxy acid could attach itself to the methylated alpha carbon of the lactide ring nor does the specification show experimental evidence that such a polymer was indeed produced. Note that lack of a working example, is a critical factor to be considered, especially in a case involving an unpredictable and undeveloped art. See MPEP 2194.

(7) The quantity of experimentation necessary:

The instant claims read on a medical article comprising an implantable substrate having a coating the coating includes a polymer or copolymer containing carboxylated PLA that contains the following structure:



where R is a group from a hydroxyl acid HO-R-COOH.

As discussed above the specification fails to provide any support for the carboxylated PLA claimed which requires that the hydroxy acid used to make the polymer is connected to the alpha methylated carbon of the lactide ring. Applicant fails to provide any information sufficient to practice the claimed invention, absent undue

experimentation. Genetech, 108 F. 3d at 1366 states that " a patent is not a hunting license. It is not a reward for search, but compensation for its successful conclusion" and "patent protection is granted in return for an enabling disclosure of an invention, not for vague intimation of general ideas that may or may not be workable.

Conclusion

No claims are allowed. Any inquiry concerning this communication or earlier communications from the examiner should be directed to James W. Rogers, Ph.D. whose telephone number is (571) 272-7838. The examiner can normally be reached on 9:30-6:00, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mike Hartley can be reached on (571) 272-0616. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618